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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,463	08/13/2001	Florence Smadja-Joffe	1721-33	5388

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,463	SMADJA-JOFFE ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-65* is/are pending in the application.

4a) Of the above claim(s) *28-50,52,55-58,60 and 63-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51,53,54,59,61 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08/08/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 08/08/2003 is acknowledged.

Claims 28-65 are pending.

Newly submitted claims 28-50, 52, 55-58, 60 and 63-65 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 12-26 of the elected group I (now claims 51, 53, 54 59 61 and 62) drawn to a method of producing a medicinal product to induce or stimulate differentiation of leukaemic cells. Newly submitted: (i) claims 28-50, 57 and 58 drawn to an *in vitro* method of regulating the differentiation of hematopoietic cells; (ii) claims 52, 55-56 ,60 63 and 64 drawn to a medicinal product ; (iii) claim 65 drawn to a method for predicting the therapeutic benefit of a medicinal product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-50, 52, 55-58, 60 and 63-65 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 51, 53, 54,59 61 and 62 read on a method of producing a medicinal product to induce or stimulate differentiation of leukaemic cells under consideration in the instant application.

The following new ground of rejection are necessitated by the amendment filed 08/08/2003

2. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 51, 53, 54 59, 61 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 51 and 53 are indefinite and ambiguous in the recitation of " a method of producing a medicinal product, said method comprising admixing in said medicinal product a polymer comprising...". It is unclear how can a method of producing a medicinal product comprises a step of admixing in said medicinal product. It is suggested that the phrase "in said medicinal product" be deleted for clarity and consistence with the disclosure of the specification. The specification disclosed that in order to produce a medicinal product a polymer and an anti-ICAM1 antibody are mixed.

5. It is improper to recite " ..and anti-ICAM1 monoclonal antibody" in claim 51. It is suggested that said phrase be changed to "... and an anti-ICAM1 monoclonal antibody".

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7 . Claims 53, 54 61 and 62 are rejected under 35 U.S.C. 103(a) as being obvious over Scott Ian (EP 295092) or Simon, J et al (DE 19802540) each in view of Legras S., et al (Blood, 1997 Vol.89, N0.6 pages 1905-1914).

DE 19802540 teaches a method of producing a medicinal product, comprising including in said medicinal product a polymer comprising disaccharide units each composed of an N-acetyl D-glucosamine structure (see entire document, Abstract in particular). DE 19802540 teaches that a polymer, comprising from 3-100 numbers of disaccharide units or various unit dose (1-10 μg/μl) was used to induce differntiation of leukaemic cells (see abstract in particular)). DE 19802540 teaches that said polymer is present in the form of a solution or in injectable form (see page particular).

EP 295092 teaches a method of producing a medicinal product, comprising including in said medicinal product a polymer comprising disaccharide units each composed of an N-acetyl D-glucosamine structure (see entire document, Abstract in particular). EP 295092 teaches that a polymer, comprising from 3-100 numbers of disaccharide units was obtained by a enzyme cleavage with hyaluronidase (see page 3, line 40-45, in particular). EP 295092 teaches that said polymer is present in the form of a solution or in injectable form(see page 4, lines 1-30 in particular). EP 295092 teaches a method of producing a medicinal product, comprising various unit dose of hyaluronic acid fragments (1-100 μg/μl) (see page 15 in particular).

It is noted that the similar method was used in the instant application to produce a medicinal product as claimed (see page 22, line 9-30 in particular).

EP 295092 or DE 19802540 does not teach a method of producing a medicinal product comprising admixing a polymer comprising effective quantity of hyaluronic acid and anti-CD44 antibody or CD44-binding fragment thereof.

Legras S., et al., teaches that anti-CD44 antibody or a CD44-binding fragment thereof enhanced the binding of hyaluronic acid with the target cell. (see entire documents, Abstract in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Legras S., et al., to those of EP 295092 or DE 19802540 to obtain a claimed method of producing a medicinal product comprising admixing a polymer comprising effective quantity of hyaluronic acid and anti-CD44 antibody or CD44-binding fragment thereof.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because anti-Cd44 antibody are capable of stimulating the binding of hyaluronic acid with the targrt cells as taught by Legras S., et al and can be used as an adjuvant compound and mixed with t a polymer comprising disaccharide units each composed of an N-acetyl D-glucosamine structure in the method of producing a medicinal product taught by EP 295092 or DE 19802540. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. The prior art does not teach or suggest the claimed invention recited in claims 51 and 59.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
October 16, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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